



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,362	02/20/2004	Shiping Wang	029714.00017	2424
79439 7590 04/16/2009 Arent Fox LLP and Cardinal Health, Inc. 1050 Connecticut Ave., N.W. Suite 400 Washington, DC 20036				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
04/16/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com

Patent_Mail@arentfox.com

IPMatters@arentfox.com

Office Action Summary

Application No.

10/783,362

Applicant(s)

WANG ET AL.

Examiner

HASAN S. AHMED

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33, 34, 43-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-31, 33, 34, 43-46, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, filed on 29 September 2008 and terminal disclaimer, filed on 21 January 2009.

* * * * *

Terminal Disclaimer

The terminal disclaimer filed on 21 January 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. application no. 11/271,666 has been reviewed and is accepted. The terminal disclaimer has been recorded.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-31, 33, 34, 43-46, 48, and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman").

Modak teaches an antimicrobial elastomeric article (*see* col. 2, lines 26-29) comprising:

- the antimicrobial of instant claims 27 and 43 (*see* col. 2, line 26);
- the elastomeric material of instant claims 27 and 43 (*see* col. 2, line 30);
- the chlorhexidine salt of instant claims 27 and 45 (*see* col. 2, line 50);
- the quaternary ammonium halide of instant claims 27 and 45 (*see* col. 2, line 61);
- the glove of instant claims 28 and 44 (*see* col. 2, line 26);
- the chlorhexidine salt and quaternary ammonium halide of instant claims 29 and 45 (*see* col. 2, lines 50 and 61); and
- the chlorhexidine salt and benzalkonium chloride of instant claims 34 and 49 quaternary ammonium halide of instant claim 27 and 49 (*see* col. 2, lines 50 and 61).

Modak discloses a glove essentially free of starch and powder, as recited in instant claims 32 and 47.

The Modak reference differs from the instant application in that it does not teach a process of extending antimicrobial activity.

McDevitt teaches an elastomeric glove (*see* paragraph 0054). The disclosed glove is comprised of:

- the antimicrobial agent of instant claims 27 and 43 (*see* paragraph 0030);
- the packaging of instant claims 27 and 43 (*see* paragraph 0189); and

- the moisture-resistant barrier container (e.g. film foil laminate) of instant claims 33 and 48 (see paragraph 0189).

Neither Modak nor McDevitt teach a desiccant, however use of desiccants in metal foil packaging was known in the art at the time the instant application was filed as evinced by Shichman (see col. 2, lines 49-51).

The reduced humidity and extended antimicrobial activity of instant claims 27 and 43 are an inherent property of foil packaging containing desiccant.

McDevitt explains that packaging the gloves is beneficial, "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph 0189.

The references are silent with respect to the time recited in instant claim 30 and the antimicrobial activity recited in instant claims 31 and 46. The prior art, as instantly claimed, discloses antimicrobial elastomeric articles packaged in foil containing desiccant (see above). Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose antimicrobial elastomeric articles packaged in foil containing desiccant, as taught by Modak in view of McDevitt, further in view of Shichman. One of ordinary skill in the art at the time the invention was made would

have been motivated to use such a process because it leads to preservation of additives (such as antimicrobial agent), as explained by McDevitt.

* * * * *

Response to Arguments

Applicant's arguments filed 29 September 2008 have been fully considered but they are not persuasive.

1. Applicants argue that Modak does not disclose a glove essentially free of powder and/or starch. Further, applicants argue that in a preferred embodiment, Modak uses corn starch as a lubricating agent. See remarks, page 11.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). Modak explicitly discloses materials other than corn starch as lubricating agents. For example, applicants disclose zinc oxide and hydroxycellulose as lubricating agents (*see* col. 2, lines 57-58); applicants provide examples of formulations that use zinc oxide and hydroxycellulose as lubricating agents, without any corn starch (*see* examples 2-4). Additionally, the Modak glove does not have any free powder because the inner coating comprising the CHG and lubricating agent also contains a polymer, e.g. silicone emulsion, which will create a uniform layer on the surface of the latex glove.

2. Applicants argue that McDevitt does not disclose, "...a packaged elastomeric article that is essentially free of powder and/or starch and is coated with at least one antimicrobial agent." See remarks, page 12.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). McDevitt was invoked for the proposition that it is known in the art to package gloves containing an antimicrobial agent in order to preserve additives and maintain a sterile environment. The other features cited by applicants were taught by Modak (*see above*).

3. Applicants argue that Shichman does not disclose gloves comprising an antimicrobial agent. See remarks, page 12.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Examiner respectfully submits that Shichman was invoked in order to show that adding a desiccant to a package in order to reduce moisture (*see col. 4, line 32*) was known in the art at the time the instant application was filed. Packaging of a glove comprising an antimicrobial material was taught by McDevitt (*see above*). It

Art Unit: 1615

is well known in the art that both packaging and reducing ambient moisture with a desiccant mitigates degradation of active ingredients and leads to increased shelf life.

4. Applicants argue that a person of ordinary skill in the art would not be motivated to combine McDevitt and Shichman with Modak because doing so would lead to redundancy of function. See remarks, page 13.

Examiner respectfully disagrees that packaging a glove coated with an antimicrobial agent with a desiccant is redundant. While Modak addresses methods of increasing the availability of CHG for longer periods of time, it is known in the art that exposure of CHG to environmental conditions such as humidity renders the CHG ineffective as an antimicrobial agent. Thus, the solution presented by Modak to increased availability of CHG does not address the vulnerability of CHG to environmental insult. It is for this reason that packaging and desiccants are used in the storage of articles with medical application.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1615

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-26 drawn to an invention nonelected with traverse in the reply filed on 21 April 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615